



CONFIDENTIAL
CORPORATE COMPLIANCE AUDIT

TENTATIVE OBSERVATIONS OF
TAP/EPSILON PDMA COMPLIANCE

TAP00063601

NOVEMBER 13 - 17, 1995

1. Original Sample Signature Cards are missing from the Epsilon records for a number of territories. For example, in territory BXA07 twenty eight cards, spanning the period August 4, 1994 through April 20, 1995 are reportedly fax copies of the original. In 13 cases, where the copy is legible, the document is clearly a copy of the original form intended for Epsilon. Although the cards are accepted by Epsilon and entered into the reconciliation process, there are no procedures allowing fax transmission of Sample Signature Cards to Epsilon.

2. The TAP sales representative sample guide prohibits whiteouts on documents. Several instances were noted where representatives altered documents with whiteout and the documents were subsequently accepted by Epsilon. In one instance, Epsilon reportedly used whiteout on ten Sample Signature Cards and wrote over the serial number because the faxed copy was not legible.

3. Highly questionable signatures were noted on a number of Sample Signature Cards. In some instances, signatures clearly did not match the practitioner name preprinted on the card. In other cases, signatures reportedly signed by the same practitioner were grossly different. Territories with questionable signatures include FFX06 (5463432), EXB09 (4107777) & (3766111), DXD06 (5130459). TAP does not have a procedure to review or verify signatures.

4. Reportedly, all sales representatives are trained in sample accountability as a condition for receiving drug samples. However, there are no procedures addressing this purported requirement in any material provided to the auditors. Although records for some representatives contained Sample Accountability Training sign-in sheets there were no records for many of the twenty sales territories reviewed.

5. PDMA requires the written request for a drug sample contain the professional designation of the practitioner making the request. The professional designation was missing from 12 Sample Signature Cards from 1 sales territory. These cards had been accepted by the TAP/Epsilon system and had become a part of the required three year record of drug distributions.

6. PDMA requires, at least annually, a complete and accurate inventory of all drug samples in the possession of representatives and requires drugs to be stored under appropriate

CALL

NO
address

Do not
include

Do not
include
TAP

Internal
about
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5
TAP

Sample
Initials
only

conditions. In a review of records of 9 sales territories active for more than twelve months, it was noted that three did not have an inventory or storage condition statement in the past 12 months as required

7. The Epsilon procedural manual for processing TAP documents states "Twice a year the District Manager (D.M.) will also do an audit and sign the inventory statement." This statement contradicts the TAP Sample Accountability Manual which states "Once a year your district manager will physically verify your inventory figures." Reportedly, neither Epsilon nor TAP has a procedure to insure that the PDMA required inventory is done at least annually. *2 months*

8. ~~PDMA requires the written request for a drug sample contain the identity of the drugs sample requested.~~ TAP used preprinted Sample Signature Cards listing Eytrin 5 X 21 Tablets and Hytrin 5 X 21 Capsules without listing the strength. Reportedly, the packages contain a combination of 1mg., 2mg., 5 mg. and 10 mg. tablets and capsules, respectively. *TAP*

9. PDMA allows distribution of drug samples to practitioners licensed to prescribe such drugs. TAP representatives distribute prescription drug samples to Physician Assistants (PA's) and Nurse Practitioners (NP's) and Epsilon has a published procedure for accepting and recording Sample Signature Cards. TAP and Epsilon use a list of states allowing sampling to PA's and NP's which reportedly was provided by PPD and is endorsed by the Abbott legal department. In a review of documents the following were noted:

a. The list is not a controlled document and neither TAP nor Epsilon has procedures to verify or maintain the list. *Put idr -*

b. Although neither Virginia nor Texas are on the TAP list for states allowing sampling, PA's in both states were sampled by TAP representatives. *50 st*

10. The TAP Sample Accountability manual states "Theft - If you were a victim of a robbery which involved samples, you must notify the police and attach a police report to an adjustment form." Reports of theft were filed by territory DXB01 and AXC06 using the Epsilon Inventory Adjustment forms on 1/17/95 and 7/5/95, respectively, without attaching a police report. Epsilon processed the losses as inventory adjustments and did not call the TAP Sample Coordinator as required in TAP BOP # S-006. Reportedly, the Epsilon Inventory Adjustment forms were completed in error, the thefts never occurred, and the inventory adjustments were used to relieve inventory. *✓*

11. The intent of congress, as expressed in the house and senate reports on PDMA was for manufacturers to use an audit system designed to detect diversion in a timely manner. In a review of the TAP Variance Trend Report it was noted that eleven (11)

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territories had variances greater than 50 units for three or more months. It should be noted that some territories had variances greater than 100 units for several months.

12. TAP SOP # ~~S-011~~ requires adjustments to inventory records greater than 10 units must be approved by Sales Administration management. Several adjustments for quantities greater than 10 units were observed to have been made without Sales Administration management approval. For example, an adjustment of 80 units of Hytrin was made to the records for territory DXD04 on 9/13/95 without the required approval.

*11/13/95
DXTG*

*How did it
↓*

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